

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	Examiner: Simon J. Oh
)	
Mahesh Chaubal, et. al.)	Group Art Unit: 1618
)	
Serial No.: 10/696,384)	
)	
Filed: October 29, 2003)	
)	
Title: Process for the Production)	
Of Essentially Solvent-Free)	
Small Particles)	
)	
Confirmation No.: 8266)	

DECLARATION OF MAHESH CHAUBAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Mahesh Chaubal, do hereby declare as follows:

1. I am a citizen of India, and I am employed as Director, Research of the company, which is a proprietor of the above-captioned application, and my employment with this company began in May 2002.

2. I hold a Ph.D. degree in Chemical Engineering from University of Maryland Baltimore County located in Baltimore, Maryland.

3. I have obtained extensive experience in the areas of drug formulation and delivery and I am the first-named inventor on U.S. Patent Application Serial No. 10/696,384.

4. I have been informed that that in a recent Office Action concerning the above-referenced application, the Examiner rejected all claims under 35 USC 112, first paragraph as not being enabling for the full scope of the claims. The Examiner stated that the specification was enabling for itraconazole, budenoside, carbamazepine, prednisolone and nabumetone but not for all poorly water soluble compounds as claimed.

5. I have read the application including the rejected claims. All claims including independent claims 1, 45 and 46 are generally directed to making small particles of a poorly water soluble, pharmaceutically active compound from a mix where the mix is simultaneously homogenized and a first solvent is continuously removed to form an aqueous suspension of small particles. This is hereinafter referred to as the process of the application.


6. Based on my experience, I can unequivocally state that one of ordinary skill in the art following the process of the application would have sufficient guidance to practice the full scope of the claims without undue experimentation.

7. The application discloses the detailed methods and assays developed by co-inventors and myself that would provide sufficient guidance to one of ordinary skill in the art to make small particles of any poorly water soluble compound.

8. We have demonstrated the applicability of the process of the application to five compounds (itraconazole, budesonide, carbamazepine, prednisolone and nabumetone) with widely different chemical structures, properties and uses. A person of ordinary skill in the art would conclude that the process could be applied to a given poorly water soluble compound without an unusual amount of effort.

9. I hereby declare that all statements made herein and of my knowledge are true and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Dated: July 27, 2007

 (MAHESH CHAUDHARY)
NAME